

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



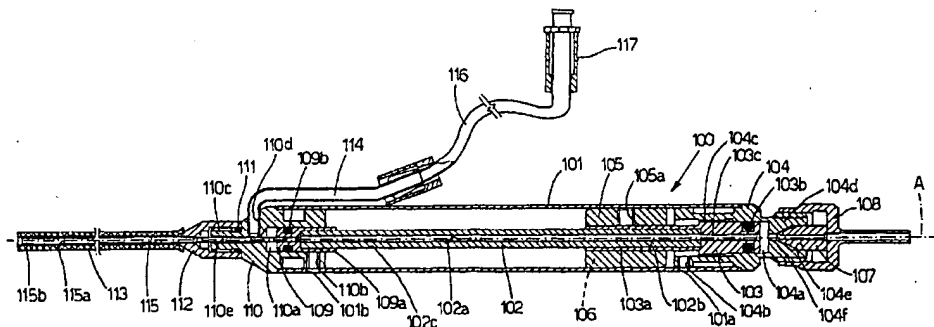
(43) International Publication Date  
19 September 2002 (19.09.2002)

PCT

(10) International Publication Number  
**WO 02/071991 A2**

- (51) International Patent Classification<sup>7</sup>: **A61F 9/007**, 9/011
- (21) International Application Number: **PCT/EP01/13004**
- (22) International Filing Date:  
9 November 2001 (09.11.2001)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
MC2001A000027 13 March 2001 (13.03.2001) IT
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- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:**  
— without international search report and to be republished upon receipt of that report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: LACRIMAL DUCT ENDOSCOPY UNIT AND METHOD



(57) Abstract: A lacrimal duct endoscopy unit (10) having a handset (100, 200) in turn having a device for optically detecting occlusions in the duct, and a device for surgically removing the occlusions.

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## LACRIMAL DUCT ENDOSCOPY UNIT AND METHOD

TECHNICAL FIELD

10       The present invention relates to a lacrimal duct endoscopy unit and method.

          The present invention also relates to a series of handsets designed for use in conjunction with the endoscopy unit which is the main object of the present  
15   invention.

          In other words, the present invention relates to a unit and method for endoscopic inspection and surgical operation of lacrimal ducts:

          The innovative unit described allows a specialist  
20   operator to inspect and, if necessary, perform surgical operations along the lacrimal duct, with the operating point kept under continuous observation.

BACKGROUND ART

          As is known, until now, internal inspection of a  
25   lacrimal duct was unthought of, the duct simply being flushed whenever possible.

          In the event of occlusion of the nasolacrimal duct in the nasal septum, a surgical operation or

dacryocystorhinostomy was performed, working from the outside, by cutting the skin and then forming a hole in the bone using a rhinostomy pincer.

In the event of an occluded duct, stents were  
5 implanted radiographically.

#### DISCLOSURE OF INVENTION

The unit and method according to the present invention provide for visually detecting and surgically operating any pre-sac stenosis, while at the same time  
10 guiding the reopening of post-sac occlusions.

It is a main object of the present invention therefore to provide a unit as claimed in Claim 1.

It is a further object of the present invention to provide a method of inspecting and, if necessary,  
15 surgically operating a lacrimal duct, as claimed in Claims 2 and 4.

It is a further object of the present invention to provide a handset designed for use in conjunction with the unit according to the invention, and as claimed in  
20 Claim 5.

It is a further object of the present invention to provide a lacrimal duct intubation device, as claimed in Claim 9.

#### BRIEF DESCRIPTION OF DRAWINGS

25 A non-limiting embodiment of the present invention will be described by way of example with reference to the accompanying drawings, in which:

Figure 1 shows, as a whole, a unit which is the main

object of the present invention, and which is designed to implement a corresponding method of inspecting a lacrimal duct and, if necessary, surgically operating any occlusions therein;

5        Figure 2 shows a first embodiment of a handset, which is a device employed in conjunction with the Figure 1 unit;

Figure 3 shows a second embodiment of a handset, also employed in conjunction with the Figure 1 unit;

10       Figure 4 shows an exploded view of the Figure 3 handset;

Figure 5 shows a first embodiment of an intubation device employed in the present invention;

15       Figure 6 shows a second embodiment of an intubation device.

#### BEST MODE FOR CARRYING OUT THE INVENTION

Number 10 in Figure 1 indicates as a whole a lacrimal duct endoscopy unit, which is the main object of the present invention.

20       In the embodiment shown, unit 10 comprises a trolley 11 mounted on four castors 12 (only three shown in Figure 1) and in turn comprising two uprights 13, and two cross members 14 fitted with castors 12.

25       Trolley 11 also comprises four shelves 15, 16, 17, 18 supported by the structure defined by uprights 13 and cross members 14.

Shelf 15 supports a mains isolator 19 extraneous to the present invention and therefore not described in

detail.

Shelf 16 supports a conventional video recorder 20 connected electrically (the electric connections not shown) to a known monitor 21 on the top shelf 18 of  
5 trolley 11.

Shelf 17 supports a conventional lighting device 22 for supplying a polarized-light beam along an optical fiber (not shown in Figure 1).

Lighting device 22 comprises a pull-out video camera  
10 23 with a handle 24 by which to extract it from a seat (not shown) formed in the body of device 22.

From video camera 23 extends a cable 25 of the type housing both an optical fiber (not shown) and a supply cable (not shown) for powering video camera 23. One end  
15 of cable 25 is fitted with a connecting device 26 for connection to a sheathed optical fiber 27 for illuminating a handset 100 of the type described in detail later on.

As described in detail later on, one portion of  
20 handset 100 is inserted endoscopically inside a lacrimal duct to optically inspect the duct and, if necessary, surgically operate any occlusions in the duct.

Operation of unit 10 is self-explanatory:

- after turning on unit 10, a specialist operator  
25 simply inserts the appropriate portion of handset 100 (see below) into the lacrimal duct;

- monitor 21 immediately displays enlarged images of the portion of the lacrimal duct housing the end portion

of optical fiber 27 extending through handset 100 (see below);

- the operator assesses the gravity of any occlusions detected, and immediately decides whether or not to operate surgically on the occlusion;
- if so, the operator operates surgically on the occlusion using handset 100 itself; and
- the operator examines the outcome of the operation, again using handset 100.

Examination and surgery may, obviously, be performed synchronously.

As stated, unit 10 also implements the innovative method of inspecting and, if necessary, operating a lacrimal duct, which is a further object of the present invention.

If necessary, the film shot by video camera 23 may be recorded on video recorder 20.

Figure 2 shows a first embodiment of handset 100, which is a further object of the present invention.

Handset 100 comprises a tubular body 101 housing an axially-sliding spindle 102, through which extends longitudinally an axial conduit 102a housing optical fiber 27 (Figure 1).

Handset 100 is substantially symmetrical with respect to an axis A.

A rear portion 102b of spindle 102 is fitted inside a nozzle 103a forming an integral part of a rear support 103 of spindle 102. Rear support 103 is substantially

piston-shaped, is fitted with a seal 103b, and slides axially, in the direction defined by axis A, inside a cylindrical chamber 104a formed in an endpiece 104 closing the rear of body 101.

5       A hole 101a is provided close to the rear end of body 101, and corresponds with a threaded hole 104b formed in the wall of endpiece 104 and in which a radial pin (not shown) is screwed to lock endpiece 104 axially. When screwed right down, the tip of the radial pin  
10       interferes with nozzle 103a to limit the travel of spindle 102.

Rear support 103 and endpiece 104 are connected by means of a screw coupling 104c.

Spindle 102 can be slid forwards or backwards  
15       manually by the operator gripping, between two fingers, a collar 105 connected integrally to spindle 102 by a radial fastening pin (not shown) screwed inside a threaded hole 105a formed in collar 105. To enable the operator's fingers to act on collar 105, and hence on  
20       spindle 102, body 101 is provided with two opposite windows 106.

Endpiece 104 terminates at the rear with an externally threaded appendix 104d having a conical seat 104e housing a cone 107 for fastening optical fiber 27  
25       (Figure 1); and cone 107 is locked inside conical seat 104e by a ring nut 108 screwed on to the outside of appendix 104d.

Endpiece 104 obviously comprises an axial through

conduit 104f for the passage of optical fiber 27, and which is obviously aligned perfectly with a conduit 103c formed in support 103 and interfaced directly with axial conduit 102a in spindle 102.

5       A front portion 102c of spindle 102 is fitted inside a nozzle 109a forming an integral part of a front support 109 of spindle 102. Front support 109 is also substantially piston-shaped, is fitted with a seal 109b, and slides, in the direction defined by axis A, inside a  
10       cylindrical chamber 110a formed in an endpiece 110 closing the front of body 101.

In other words, endpieces 104 and 110 close the rear end and front end of body 101 respectively.

A hole 101b is provided close to the front end of  
15       body 101, and corresponds with a threaded hole 110b formed in the wall of endpiece 110, which, as stated, is inserted inside the open front end of body 101; and a second threaded pin (not shown) is screwed inside hole 110b to prevent any axial movement of endpiece 110.

20       At the front, endpiece 110 comprises an externally threaded, substantially cylindrical appendix 110c.

With the interposition of a seal 111, a special ring nut 112 is screwed on to appendix 110c and supports a cannula 113 for insertion inside a lacrimal duct (not  
25       shown).

Endpiece 110 also has a lateral hole 110d, in which is fitted a rigid tube 114 for feeding irrigation fluid into a through conduit 110e extending axially through



endpiece 110. The irrigation fluid flows into cannula 113, which houses a drilling tool 115 rotated and fed axially forward by the rotation and axial feed of spindle 102, with which drilling tool 115 is integral.

5       A through conduit 115a extends longitudinally through drilling tool 115, and houses optical fiber 27 (not shown in Figure 2), which, to illuminate and pick up images of the lacrimal duct, must extend up to the end 115b of drilling tool 115.

10       Rigid tube 114 is connected to a flexible tube 116 fitted on the end with a bracket 117 for fast fit and removal of a syringe (not shown) containing the lacrimal duct irrigation fluid.

15       Figures 3 and 4 show a second embodiment of a handset 200.

Handset 200 comprises a substantially tubular body 201 (Figure 4a) symmetrical with respect to a longitudinal axis B, having two opposite openings 201a, 201b, and shaped for improved grip of handset 200 by the  
20       operator.

An endpiece 202 is inserted inside opening 201a up to a shoulder 201c formed on the wall of a through conduit 201d extending longitudinally through body 201, from opening 201a to opening 201b.

25       Endpiece 202 is fixed to body 201 in the same way as in the first embodiment shown in Figure 2, i.e. by means of a fastening pin (not shown), which fits through a hole (not shown) in body 201, and screws into a threaded hole

(not shown) in endpiece 202.

Inside, endpiece 202 also has a longitudinal conduit 202a, which is also coaxial with axis B, and at least one portion of which is threaded to screw on a supporting member 203 for a bored tool 204. More specifically, supporting member 203 comprises an outer shell 205 in which is inserted a bored bushing 206.

As shown in detail in Figure 4a, bored tool 204 is therefore supported at one end by outer shell 205, and at the other end by bored bushing 206. Outer shell 205 can be divided theoretically into a substantially truncated-cone-shaped first portion 205a, and a cylindrical second portion 205b having an external thread by which, as stated, to screw supporting member 203 to endpiece 202.

Body 201 also has a lateral opening 201e through which to supply irrigation fluid in the same way as in Figure 2.

A further endpiece 208 is inserted inside opening 201b, and has a shoulder 208a which mates with the edge of opening 201b.

At least one portion of endpiece 208 projecting from body 201 has a thread for the reasons explained in detail later on.

Figures 4b and 4c show two alternative embodiments of handset 200.

The first embodiment in Figure 4b employs only one optical fiber (not shown) for simply detecting optically the condition of the lacrimal duct, while the second

embodiment in Figure 4c employs a second optical fiber (not shown) for conveying a laser beam produced by a generator (not shown).

More specifically, and firstly with reference to  
5 both Figures 4a and 4b, body 201 is closed at opening 201b by a closing device 209.

Closing device 209 comprises a bored, internally threaded ring nut 210, a bored plug 211 inserted inside ring nut 210, and a tube 212 surrounded by a sealing ring  
10 212a, and, by means of the internal thread of ring nut 210, screws on to the external thread of endpiece 208.

Ring nut 210 has a hole 210a through which is inserted a tube 213 for insertion of the optical fiber (not shown), which, in this case, as stated, merely  
15 serves to determine the condition of the lacrimal duct optically.

The optical fiber is fixed firmly using a bored cone 214 partly threaded on the outside and which fits on to tube 213; a spacer member 215; and an internally threaded  
20 ring nut 216 for receiving spacer member 215 and which screws on to the threaded portion of cone 214.

As stated, in addition to the devices housing and supporting a first image-detecting optical fiber, the Figure 4c embodiment is also designed to insert inside  
25 handset 200 a second optical fiber (not shown) for conveying a laser beam by which to remove any occlusions detected in the lacrimal duct.

Consequently, in addition to hole 210a, plug 211

also has a further hole 210b in which is inserted a respective tube 217.

As before, tube 217 is provided with a cone 218, a spacer member 219, and an internally threaded ring nut  
5 220 for receiving spacer member 219 and which screws on to the threaded portion of cone 218.

By means of the second solution shown in Figures 4a and 4c, the operator, on detecting an occlusion, removes it using a laser beam conveyed by the second optical  
10 fiber (not shown) through tube 217.

In a further embodiment (not shown) a handset comprises trigger means for shooting forward a punching tool to remove particularly tough occlusions.

Figure 5 shows a first embodiment of an intubation  
15 device 300.

Intubation device 300 is substantially a tubular device, made of plastic material, for intubation of the lacrimal ducts connecting the eye to the nasal passages, and may advantageously, though not necessarily, be made  
20 of a perfluoroethylenepropylene (FEP) or tetrafluoroethylene (Teflon ®) copolymer, which, as is known, have a low friction coefficient, and are water-repellent, chemically stable, and biocompatible.

Intubation device 300 is used for post-operative  
25 treatment of lacrimal duct stenoses.

More specifically, intubation device 300 comprises a substantially tubular portion 301 with three encapsulated stripes (not shown) made of radiopaque material, such as

BaSO<sub>4</sub>.

At the proximal end 301a, portion 301 has a conical flared portion 301 with two holes 303 (only one shown in Figure 5). Conical flared portion 302 prevents intubation device 300 from slipping completely inside the lacrimal duct, while holes 303 provide for fixing the intubation device to the patient's skin by means of two stitches.

The distal end 301b is tapered to permit nontraumatic insertion of intubation device 300 inside the lacrimal duct, and is open to allow liquid medication to flow through freely. Since the type of intubation device 300 required in each case cannot be established beforehand, a kit is provided containing intubation devices 300 of different diameters and lengths, and which may be packaged in a single blister pack.

Generally speaking, use of intubation device 300 is dependent on a surgical operation performed using unit 10 in Figure 1.

Surgery using unit 10 is performed with a local anesthetic, with the exception of children.

First of all, the lacrimal duct is dilated to insert, for example, handset 100 or 200; and the lacrimal duct is then examined to locate the stenosis, which is opened using handset 100 or 200. If handset 100 is used, with the aid of cannula 113, the duct is flushed immediately with antibiotics, steroids or diluted betadine. At this point, intubation device 300 is inserted inside the lacrimal duct to ensure correct

epithelization of the operated portion of the duct. Intubation device 300 is inserted manually by distal end 301b and up to flared proximal end 301a. By means of stitch holes 303, conical flared portion 302 may be fixed  
5 firmly to the patient's skin to prevent intubation device 300 from becoming dislodged. During the post-operative period, general antibiotics and decongestive nose drops are administered. If necessary, intubation device 300 may be removed temporarily to flush the lacrimal duct with  
10 local antibiotics, and, once removed, must be replaced with a new one.

Intubation device 300 is supplied sterile in a disposable package.

Figure 6 shows an alternative embodiment of  
15 intubation device 300.

This differs from the Figure 5 embodiment by the distal end 301b being closed, and by portion 301 having a number of holes 304 a given distance apart.

Given a set of intubation devices 300 with  
20 differently spaced holes 304, liquid medication can be injected at various points along the lacrimal duct. Initially, however, liquid medication is injected through conical flared portion 302.

The main advantage of the present invention lies in  
25 occlusion of the nasolacrimal duct no longer requiring a dacryocystorhinostomy from the outside, by cutting the skin and subsequently forming a hole in the bone using a rhinostomy pincer.

## CLAIMS

1) A lacrimal duct endoscopy unit, characterized by comprising:

- 5       - a lighting device for supplying a polarized-light beam along an optical fiber;
- a video camera connected electronically to the lighting device and for picking up images; and
- a handset for inspecting lacrimal ducts and
- 10       operating on any occlusions detected therein; the handset being connected electronically to the video camera by the optical fiber.

2) A method of operating on lacrimal ducts, characterized by inserting into a lacrimal duct an

15       optical fiber connected electronically to a video camera to endoscopically inspect the condition of the lacrimal duct.

3) A method as claimed in Claim 2, wherein, in the event of occlusion of the lacrimal duct, a device for

20       surgically operating on the occlusion is also inserted into the lacrimal duct.

4) A method of operating on lacrimal ducts, the method comprising the steps of:

- dilating the lacrimal duct to permit insertion of
- 25       one end of a handset supporting an optical fiber;
- optically inspecting the lacrimal duct to locate the stenosis, which is opened by means forming part of the handset; and

- inserting an intubation device into the lacrimal duct to ensure correct epithelization of the surgically operated portion of the lacrimal duct.

5) A handset for lacrimal duct endoscopy, the handset comprising means for optically detecting occlusions in the duct, and means for surgically removing the occlusions.

6) A handset as claimed in Claim 5, wherein the means for optically detecting occlusions in the lacrimal duct comprise at least one optical fiber; and wherein the means for surgically removing the occlusions comprise a mechanical drilling tool fed forward axially by a feed device.

7) A handset as claimed in Claim 6, wherein a punching tool is shot axially forward by trigger means to remove the occlusion.

8) A handset as claimed in Claim 5, wherein the means for optically detecting occlusions in the lacrimal duct comprise at least one optical fiber; and wherein the means for removing the occlusions comprise an optical-fiber laser device.

9) A lacrimal duct intubation device comprising a substantially tubular portion having a conical flared portion at the proximal end, and a tapered distal end permitting nontraumatic insertion of the intubation device inside the lacrimal duct.

10) An intubation device as claimed in Claim 9, wherein the distal end is closed; and wherein the



substantially tubular portion has a number of holes.

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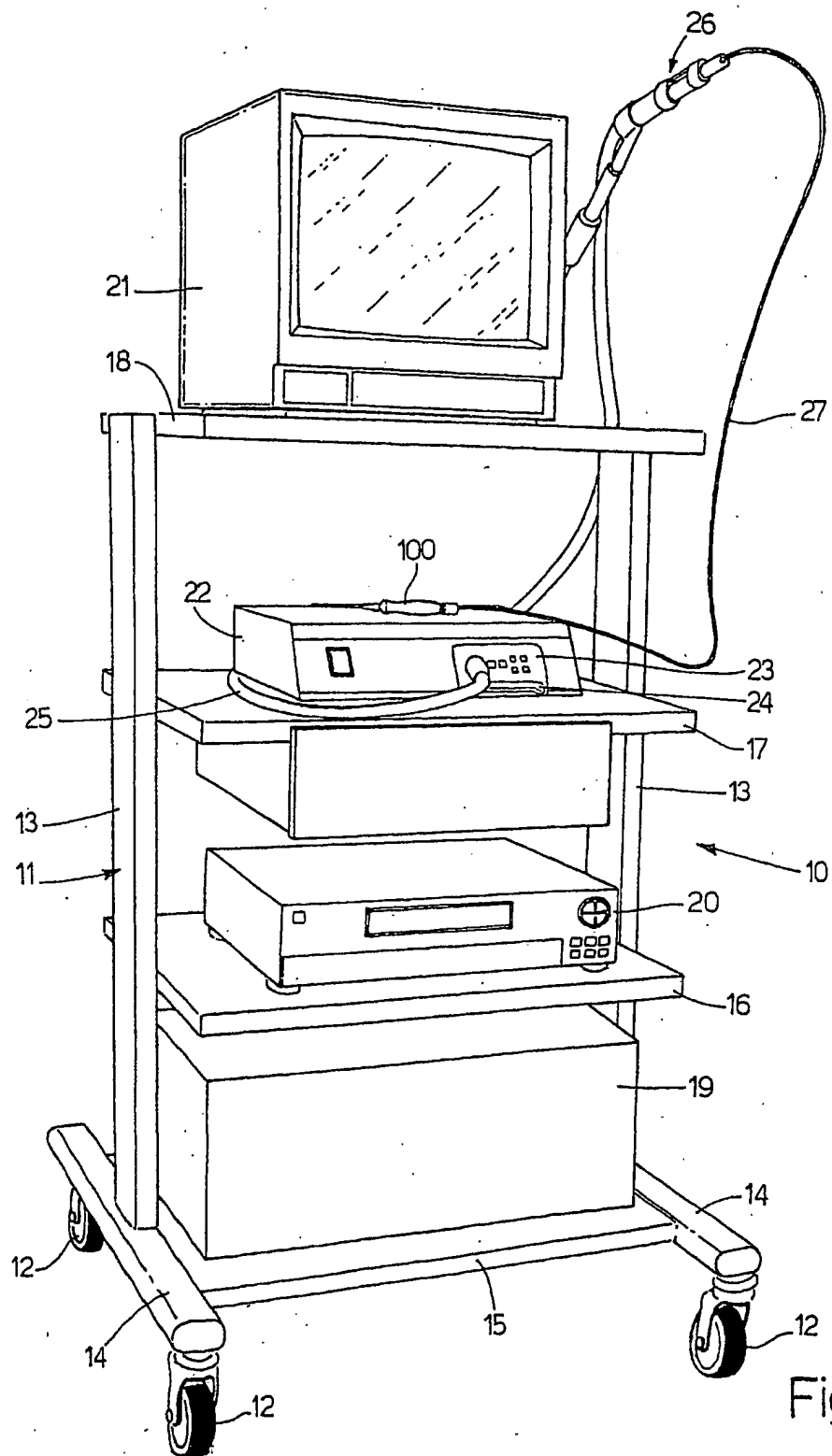


Fig.1

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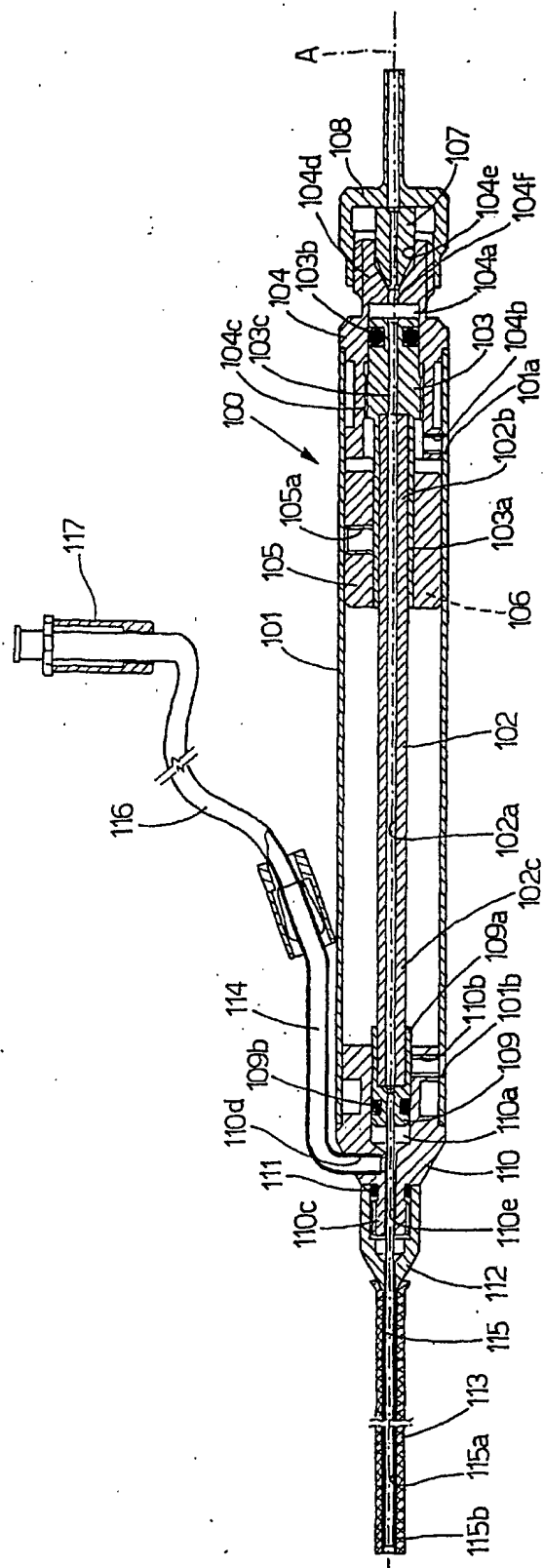
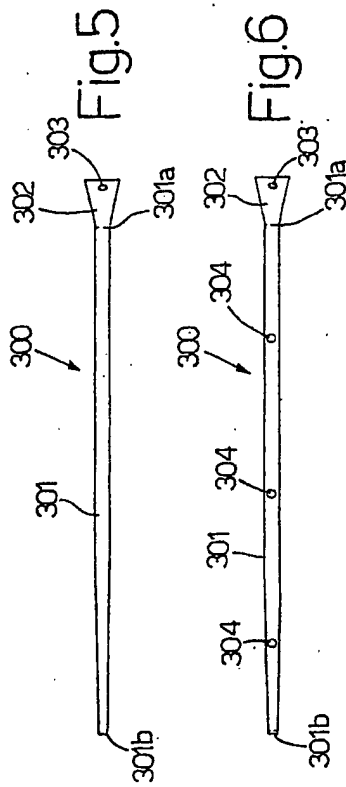
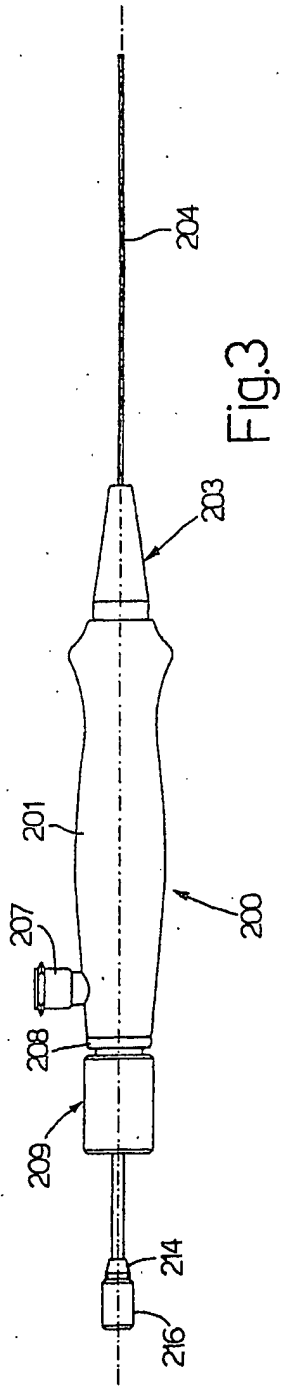


Fig.2

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